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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,409	05/11/2001	Kevin P. Anderson	ISPH-0569	7066

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EXAMINER	
GUZO, DAVID	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,409	ANDERSON ET AL.	
	Examiner	Art Unit	
	David Guzo	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-26 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 28-31* is/are rejected.

7)☒ Claim(s) *24-26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

The Terminal Disclaimers over US Patents 6,608,191 and 6,423,489 have been received, are acceptable and have been entered. The obviousness type double patenting rejections over these patents are withdrawn. However, the issue of common ownership at the time the invention was made and potential rejections of the claims under 35 USC 103(a) (see below) remain to be resolved.

Claims 23 and 28 are directed to an invention not patentably distinct from claim 1 of commonly assigned 6,608,191 and claims 1 and 7 of commonly assigned 6,423,489. Specifically, the claims are not patentably distinct for the reasons recited in the obviousness type double patenting rejections of record in the previous Office Action.

Claims 23 and 28 are directed to an invention not patentably distinct from claim 1 of commonly assigned 6,608,191 and claims 1 and 7 of commonly assigned 6,423,489. Specifically, the claims are not patentably distinct for the reasons recited in the obviousness type double patenting rejections of record in the previous Office Action.
The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP 2302). Commonly assigned 6,423,489 and 6,608,191, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35

U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. **Failure to comply with this requirement will result in a holding of abandonment of the application.**

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Applicants have again not responded to this requirement in the response filed 4/15/04. **Any response to this Office Action that does not include a response to this requirement will be considered non-responsive.**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S.

Patent No. 6,174,868. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite antisense oligonucleotides comprising SEQ ID NO:6. It is noted that applicants do not define, in the instant specification, how a composition comprising an antisense oligonucleotide (SEQ ID NO:6) in a form suitable for subcutaneous administration differs from any other composition suitable for *in vivo* use. Therefore, it must be considered, absent evidence to the contrary, that the claims read on a composition comprising the recited oligonucleotides with any pharmaceutically acceptable carrier.

The instant composition claims are obvious in view of claims 1-11 of the '868 patent because the antisense oligonucleotide (SEQ ID NO:6 or at least a 5' portion of SEQ ID NO:6) recited in the '868 patent and the same oligonucleotide claimed in the instant application are complementary to the translation initiation start site of the HCV genome and are designed to be used to inhibit expression of the HCV genome in cells in patients. It is noted that the instant claims recite compositions comprising **any oligonucleotide** comprising SEQ ID NO:6; the term oligonucleotide includes unmodified **and modified** oligonucleotides (as per applicants definition in the instant specification, p. 10). Therefore, the ordinary skilled artisan would have been motivated to incorporate the oligonucleotides recited in the '868 patent (SEQ ID NO:6) into a pharmaceutically acceptable composition suitable for *in vivo* use (such as by subcutaneous administration) and use the recited oligonucleotide to inhibit HCV expression because the antisense oligonucleotide targets an essential region for HCV gene expression and is designed to be used to inhibit HCV gene expression in patients.

It would have been obvious for the ordinary skilled artisan to do this because the recited antisense oligonucleotide is targeted against a region critical in HCV gene expression and could be used to treat patients suffering from HCV infection. Given the claim in the '868 patent and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be assumed that the skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claims 23 and 28 are directed to an invention not patentably distinct from claims 1-11 of commonly assigned US 6,174,868. Specifically, the claims are not patentably distinct for the reasons recited in the above obviousness type double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned US 6,174,868, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. **Failure to comply with this requirement will result in a holding of abandonment of the application.**

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Claims 23 and 28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-5 of copending Application No. 10/457,304 and over claims 2-5 of copending Application No. 10/454,293. Although the conflicting claims are not identical, they are not patentably distinct from each other because all sets of claims recite an oligonucleotide (which can be an RNA or SEQ ID NO:6) designed to hybridize to HCV genomic or messenger RNA. The instant claims recite compositions comprising an oligonucleotide (comprising SEQ ID NO:6) in a pharmaceutically acceptable carrier while the claims in the '304 and '293 applications recite RNA oligonucleotide compounds (including SEQ ID NO:6) within the same size range of the instantly claimed oligonucleotides and recite that said RNAs specifically hybridize to HCV genomic or messenger nucleic acids and inhibit HCV gene expression. Therefore, the ordinary skilled artisan would have been motivated to incorporate the RNAs recited in the '304 and '293 applications (SEQ ID NO:6) into a pharmaceutically acceptable composition suitable for *in vivo* use (such as by subcutaneous administration) and use the recited oligonucleotide to inhibit HCV expression because the antisense oligonucleotides are designed specifically to be used to inhibit HCV gene expression. It would have been obvious for the ordinary skilled

artisan to do this because the recited oligonucleotides are designed to inhibit HCV gene expression *in vivo* and because SEQ ID NO:6, in particular, is targeted against a region critical in HCV gene expression (polyprotein initiation codon region) and could be used to treat patients suffering from HCV infection. Given the claims in the '304 and '293 applications and the level of skill of the ordinary skilled artisan at the time the invention was made, it must be assumed that the skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites a composition consisting of one component (SEQ ID NO:6). It is unclear how a composition of matter (which is usually defined as containing two or more components) can only contain a single oligonucleotide (SEQ ID NO:6). Claim 28 is also unclear in that applicants recite the composition in a "...form suitable for subcutaneous administration" because it is unclear whether the oligonucleotide has been modified in some manner to make it into a "form suitable for subcutaneous administration" or whether the oligonucleotide is in some formulation (with other components) which

renders it suitable for subcutaneous administration. Claims 29-31 are also rejected as they depend from rejected Claim 28.

No Claims are allowed.

Claims 24-26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID GUZO
PRIMARY EXAMINER

David Guzo
June 19, 2004